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Certified by

Jon W Dudas

Acting Under Secretary of Commerce
for Intellectual Property
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PROVISIONAL PATENT APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 CFR 1.53(b)(2).

Docket Number	7414-16	Type a plus sign (+) inside this box =>	+

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TITLE OF THE INVENTION (230 characters max)

PROSTHESIS

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ENCLOSED APPLICATION PARTS (check all that apply)

X	Specification Number of pages	8				
X	Drawing(s) Number of pages	7				
				X	Other (specify)	2 postcards

METHOD OF PAYMENT (check one)

X	Please charge Deposit Acct. No. 50-0951 to cover the provisional filing fees.		PROVISIONAL FILING FEE AMOUNT($)	$80.00
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

[X] No

[ ] Yes, the name of the U.S. Government agency and the Government contract number is:

Applicant claims Small Entity Status.

[ ] No

[X] Yes

Respectfully submitted,

SIGNATURE _____ Date June 27, 2003

TYPED or PRINTED NAME Amy A. Ostrom, Ph.D. REGISTRATION NO. (if appropriate) 52,088

[ ] Additional inventors are being named on separately numbered sheets attached hereto

PROVISIONAL APPLICATION FILING ONLY

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PROSTHESIS

FIELD OF THE INVENTION

The invention relates generally to the fields of biomedical engineering and prosthetics. More particularly, the invention relates to a prosthesis useful as a replacement for aortic sinuses and in some applications, a replacement for an aortic valve and aortic sinuses.

BACKGROUND

Blood flow from the left ventricle to the aorta is regulated by the tricuspid aortic valve. As its name suggests, this valve includes three crescent-shaped leaflets that each move between a closed position where blood cannot pass and an open position where blood can pass. In the closed position, the margins of the three leaflets come together flushly to seal the passage between the left ventricle and the aorta. In the open position, each of the leaflets moves into a cavity, termed a sinus of Valsalva, allowing blood to flow through the valve. Two of the sinuses include coronary ostia for the right and left coronary arteries. Because the third sinus does not contain an ostia, it is referred to as the non-coronary sinus.

Malfunction of the aortic valve can have severe clinical consequences. Fortunately, surgical procedures and prostheses have been developed for replacing defective aortic valves. These procedures often involve excision of the sinuses of Valsalva and reattachment of the coronary arteries to the prosthesis at a convenient location. While aortic valve replacement is usually successful, the results may be less than ideal because removal of the sinuses of Valsalva and suboptimal placement of the coronary artery anastomoses can have a negative effect on the fluid dynamics of blood flow.

SUMMARY

The invention relates to the development of a prosthesis useful in aortic valve replacement surgery. The prosthesis includes a portion fashioned into sinuses that resemble the sinuses of Valsalva. Ostia which serve as re-attachment sites for the left and right coronary arteries are optimally located on the sinuses. The prosthesis can also include a valve portion for regulating blood flow, and artificial vessels extending from

the ostia to aid in coronary artery attachment, e.g., in situations where the coronary arteries are too short to reach the ostia. The prosthesis is advantageous because its sinuses and ostia mimic the natural anatomy and allow optimal blood flow.

In one embodiment of the prosthesis of the invention, the aortic root of the valve is attached to the bottom of the sinus portion with the valve seated inside of the sinus. The prosthesis can thus be manufactured, packaged, and delivered to the surgeon as a single unit. During an aortic valve replacement procedure, a surgeon attaches the base of the prosthesis in the same manner as done with current prosthetic valves, i.e., most of the aortic root is excised, the prosthesis is attached to the normal tissue in the left ventricular outflow tract, and the coronary arteries are removed. Once the base of the prosthesis has been attached, the upper portion of the prosthesis is then attached to the aortic arch and each coronary artery is attached to an ostium or an artificial vessel attached to the ostium. Thus use of the prosthesis of the invention avoids the conventional step of fashioning and attaching an artificial vessel between the left ventricle and aortic arch. Moreover, the reduced number of surgical steps should reduce the amount of time a patient must be on cardio-pulmonary bypass, and should therefore improve the outcome of the procedure.

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, suitable methods and materials are described below. All publications, patent applications, patents, and other references mentioned herein are incorporated by reference in their entirety. The particular embodiments discussed below are illustrative only and not intended to be limiting.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A is a schematic end view of a prosthetic prosthesis of the invention having artificial vessels extending from the ostia.

FIG. 1B is a schematic front view of a prosthetic prosthesis of FIG. 1A.

FIG. 2A is a schematic end view of a prosthetic prosthesis of the invention having ostia to which a vessel (e.g., coronary artery) can be connected.

FIG. 2B is a schematic front view of a prosthetic prosthesis of FIG. 2A.

FIG. 3 is a series of computer-generated images showing velocity streamlines of a prosthesis including sinuses (A) versus one without sinuses (B), and wall shear lines in a prosthesis including sinuses (C) versus one without sinuses (D).

FIG. 4 is a graph of the wall shear vs. time from a sinus-containing prosthesis versus one without sinuses.

FIG. 5 is a diagram illustrating height of the sinuses (hs) measured to be 19.9 - 24.6 mm (1.76 x Rb, with the mean Rb = 11.3 - 14 mm). The distance the sinuses extend out from the normal lumen of the aortic valve ring can be measured by the total sinuses depth (ds) minus the radius of the base of the ring (Rb), namely 5.2 - 6.4 mm (ds - Rb; with ds = 1.46 x Rb = 16.5 to 20.4).

DETAILED DESCRIPTION

The invention is directed to a prosthesis 10 for use in aortic valve replacement procedures. As shown in FIGs. 1A, 1B, 2A, and 2B, exemplary embodiments of the prosthesis 10 feature a vessel-like structure 14 that includes a first end 16 adapted for surgical attachment to a left ventricle, a second end 18 adapted for surgical attachment to an aorta, and interposed between the first and second end, a sinus portion 20 resembling the sinuses of Valsalva in a human aortic valve. In the embodiments shown in FIGs. 1A, 1B, 2A, and 2B, the sinus portion 20 of the prosthesis 10 includes three sinus cavities, although it could include other numbers of cavities (e.g., 1, 2, 4, 5 or more). Two of the sinus cavities 20 shown each have an ostium 22 suitable for connecting a vessel 26 such as a coronary artery or an artificial vessel (as in the embodiment shown FIGs. 1A and 2B) to which a coronary artery can be attached.

In embodiments where one or more artificial vessels are attached to the ostia, suitable artificial vessels may be formed from any suitable material (e.g., TEFLON™ or other similar material). The artificial vessels may be synthetic or non-synthetic, or any combination thereof. The artificial vessels may be adapted to be coupled to one or more coronary arteries of a subject. The diameter and length of the artificial vessels is determined similar to the method described above for sinus size determination and would be sized to correspond with the diameter of the optimal coronary ostium. An average measurement for a coronary artery is 2.5-3 mm and this measurement would be used as a starting point for designing artificial vessel extensions.

The prostheses 10 of FIGs. 1A, 1B, 2A, and 2B also include a valve 24 for regulating fluid flow. The valve 24 is located toward the first end 16 of the vessel-like structure 14 so that it is proximal to the ventricle when implanted. The valve 24 can be a separate component that is inserted into the prosthesis or it can be integral (i.e., formed as one unit with the rest of the vessel-like structure). Several suitable valves are known, including those used previously for aortic valve replacement. For example, the valve can be one formed from animal tissue or one that is not. The valve may be synthetic or non-synthetic, or any combination thereof. In one example, the valve may be formed from DACRON™ or other similar material. It can take the form of a caged ball valve, a tilting disc valve, a bileaflet valve, or a trileaflet valve.

Referring to FIG. 3, computer modeling showed that a sinus-containing prosthesis having optimally located ostia exhibited better fluid dynamics than did a conventional prosthesis. Velocity streamlines of a prosthesis including sinuses are shown in FIG. 3A. Velocity streamliners of a prosthesis without sinuses is shown in FIG. 3B. Wall shear lines in a prosthesis including sinuses versus one without sinuses are shown in FIGs. 3C and 3D, respectively. These experiments showed that the prosthesis with sinuses and optimally placed ostia provides better flow and less wall shear than the prosthesis without sinuses. These results are also illustrated in the data shown in Fig. 4.

Optimal placement of each ostium 22 is determined based on correlations of certain coronary attachment sites and those individuals having cardiac complications (e.g., quadruple and triple bypass surgery, pacemakers, etc.). Optimal placement of the ostia was found to be in the range of about 10-20 mm (e.g., 15 mm) from the base of the sinus. The base is the portion of the sinus proximal to the ventricle that first starts to bulge. The components of the prosthesis can be made of any suitable material. Several are known in the art. See The Aortic Valve by Mano J. Thubrikar and Peter P. Klemchuk, 1989 CRC Press Boca Raton, FL.

The size of the prosthesis will vary depending on the particular application. Generally, the prosthesis is sized to mimic the size of the corresponding components of the natural tissue being replaced. The sinuses may be of any size appropriate for the size of the subject to receive the prosthesis. In one embodiment, the size of the sinuses is based on normal, average measurements as described in The Aortic Valve by Mano J.

Thubrikar and Peter P. Klemchuk, 1989 CRC Press Boca Raton, FL. These normal, average measurements can be used to construct a range of prostheses of different sizes from which a surgeon can choose the most appropriate size for the subject.

The prosthesis described above is designed for surgical implantation into an animal or human subject in need of an aortic valve replacement. In an exemplary method of implanting the prosthesis in a subject, the subject is prepared for surgery as in conventional aortic valve replacement surgery. For example, the subject is first anesthetized. The heart is then surgically exposed and arrested, and the subject is connected to a cardio-pulmonary (heart-lung) bypass machine. The defective aortic valve and sinuses of Valsalva are excised leaving the left ventricle and aorta unconnected, and the left and right coronary articles are detached from the sinuses. The first end of the prosthesis is then surgically attached to the ventricle to close off the opening left by removal of the valve, and the second end is attached to the aorta. The coronary arteries are then attached to the ostia (or, in some embodiments, to the artificial vessels extending from the ostia) optimally located in the sinuses of the prosthesis. The heart is restarted, the cardio-pulmonary bypass removed, and the surgical site closed.

While the above specification contains many specifics, these should not be construed as limitations on the scope of the invention, but rather as examples of preferred embodiments thereof. Many other variations are possible. For example, although the foregoing embodiments mainly relate to aortic valve repair/replacements, this technology might also be applied to other valve replacement and vessel repair procedures.

CLAIMS

1. A prosthesis comprising:

a vessel-like structure having a first end adapted for surgical attachment to a left ventricle, a second end adapted for surgical attachment to an aorta, and, interposed between the first and second ends, a sinus portion resembling the sinuses of Valsalva in a human aortic valve.

2. The prosthesis of claim 1, wherein the sinus portion comprises an ostium.

3. The prosthesis of claim 2, wherein the ostium is connected to an artificial vessel.

4. The prosthesis of claim 1, wherein the sinus portion comprises three sinus cavities.

5. The prosthesis of claim 4, wherein at least two of the sinus cavities each comprise an ostium.

6. The prosthesis of claim 1, wherein the vessel-like structure further comprises a valve for regulating fluid flow.

7. The prosthesis of claim 6, wherein the valve comprises animal tissue.

8. The prosthesis of claim 6, wherein the valve does not comprise animal tissue.

9. The prosthesis of claim 8, wherein the valve is selected from a caged ball valve, a tilting disc valve, a bileaflet valve, and a trileaflet valve.

10. A method for replacing at least one aortic sinus in a subject, the method comprising the steps of:

(A) providing a subject; and

(B) implanting the prosthesis of claim 1 into the subject.

ABSTRACT

A prosthesis includes a vessel-like structure having a first end adapted for surgical attachment to a left ventricle, a second end adapted for surgical attachment to an aorta, and, interposed between the first and second ends, a sinus portion resembling the sinuses of Valsalva in a human aortic valve.

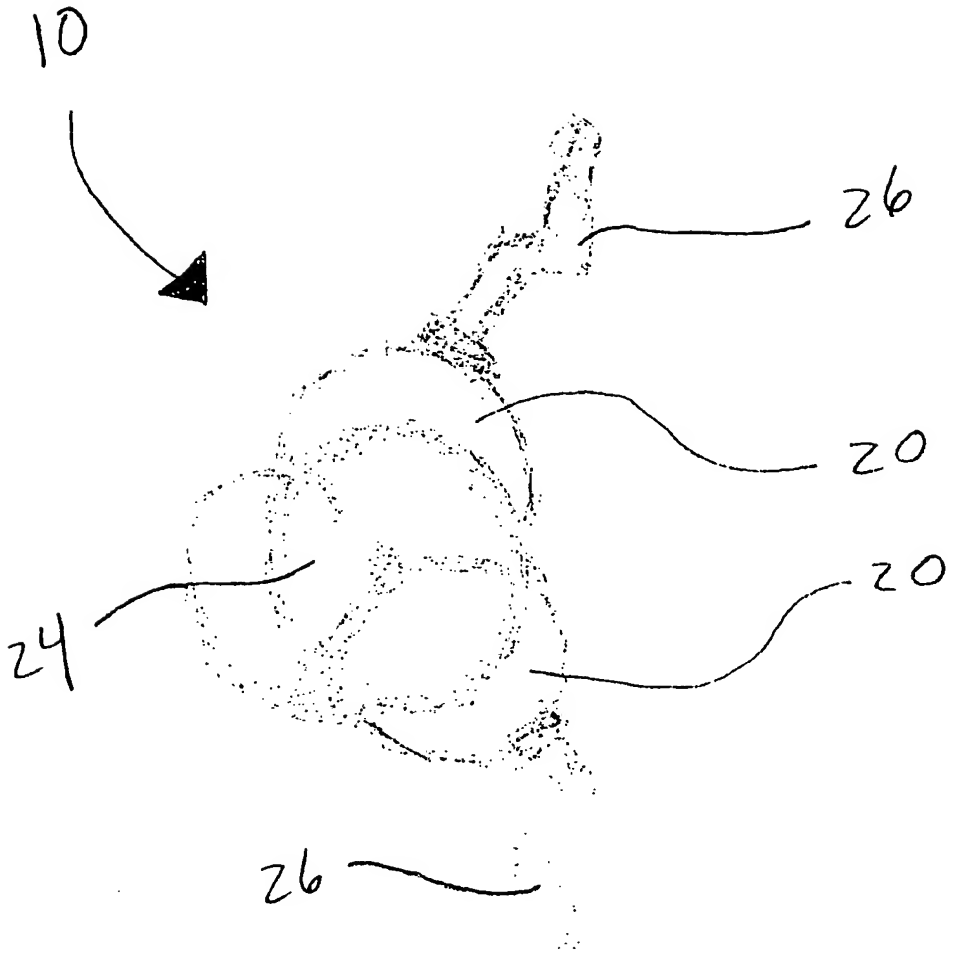

FIG. 1A

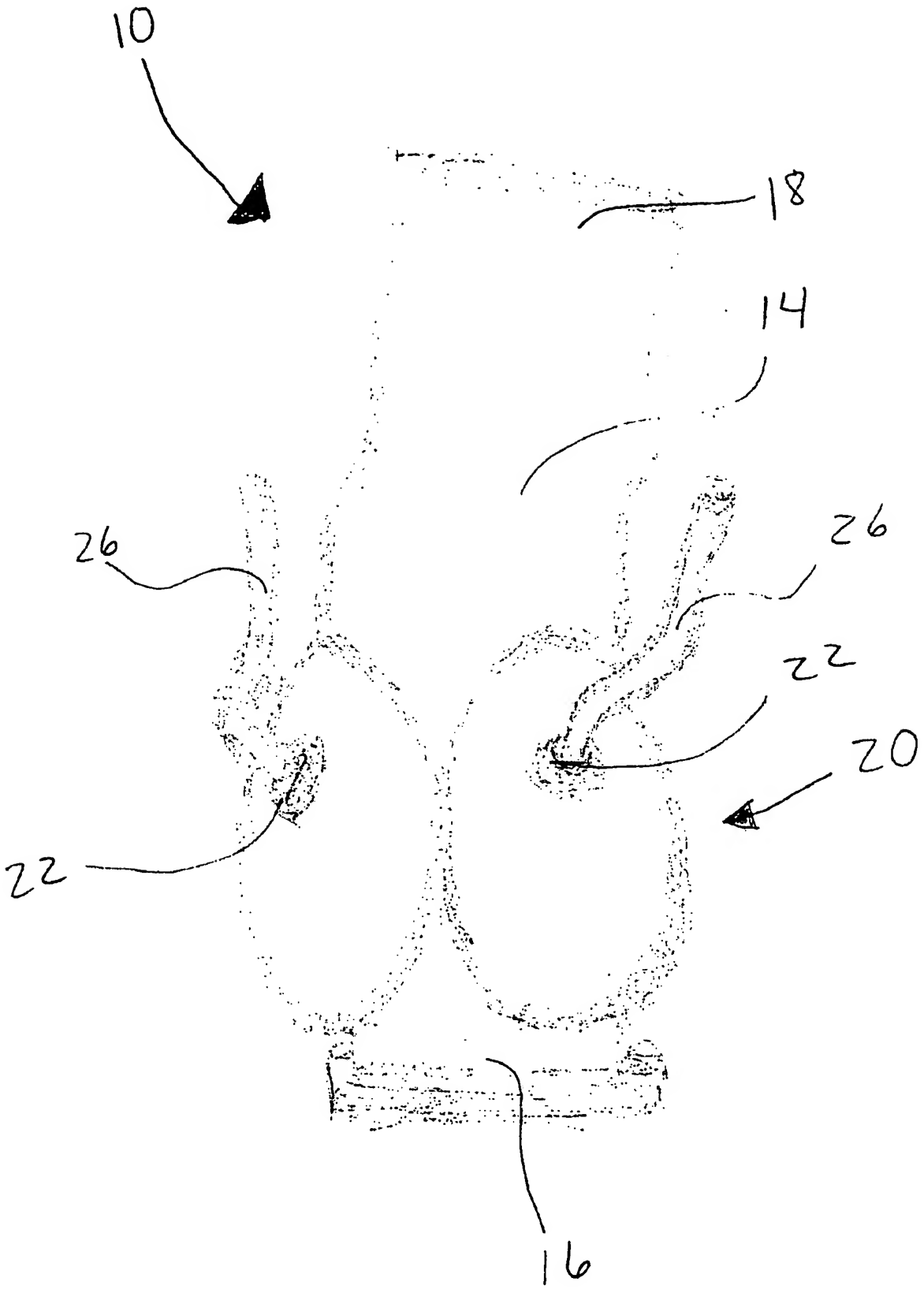

FIG. 1B

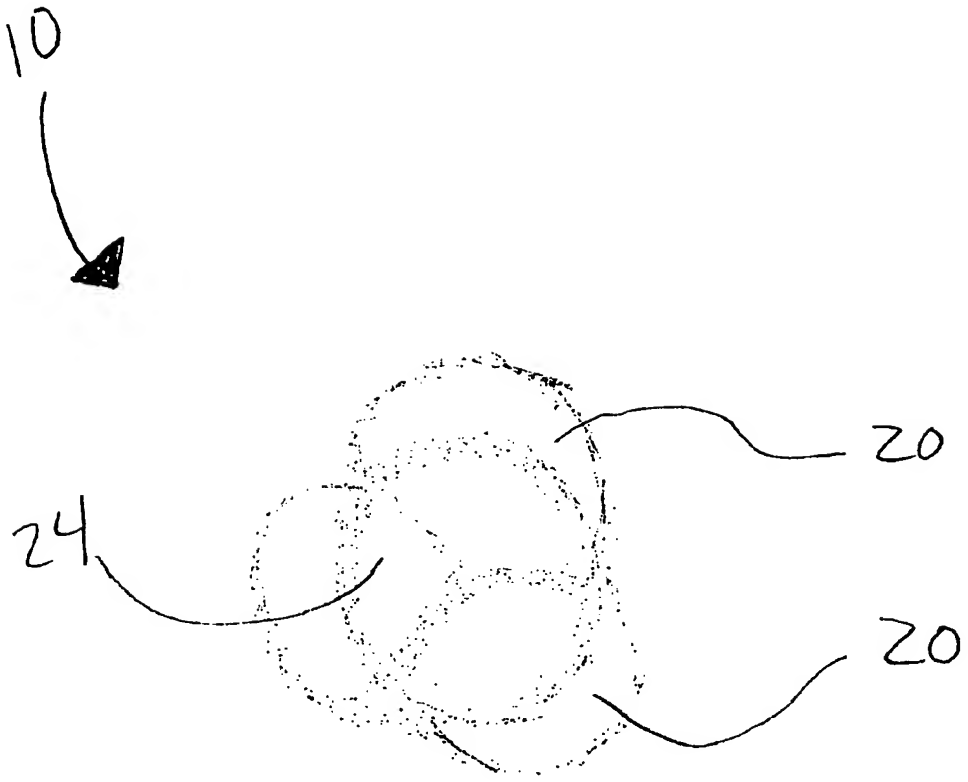

FIG. 2A

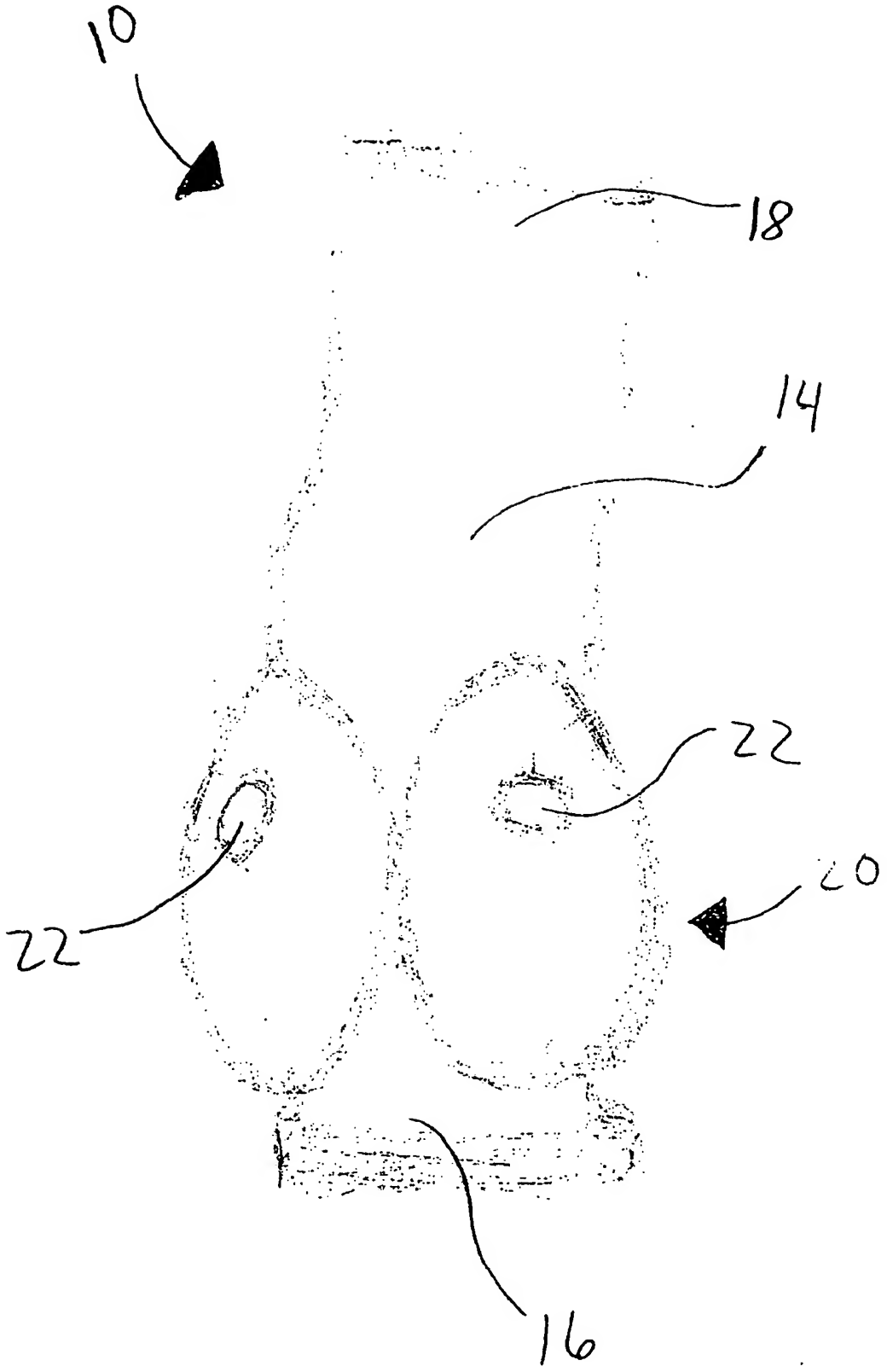

FIG. 2B

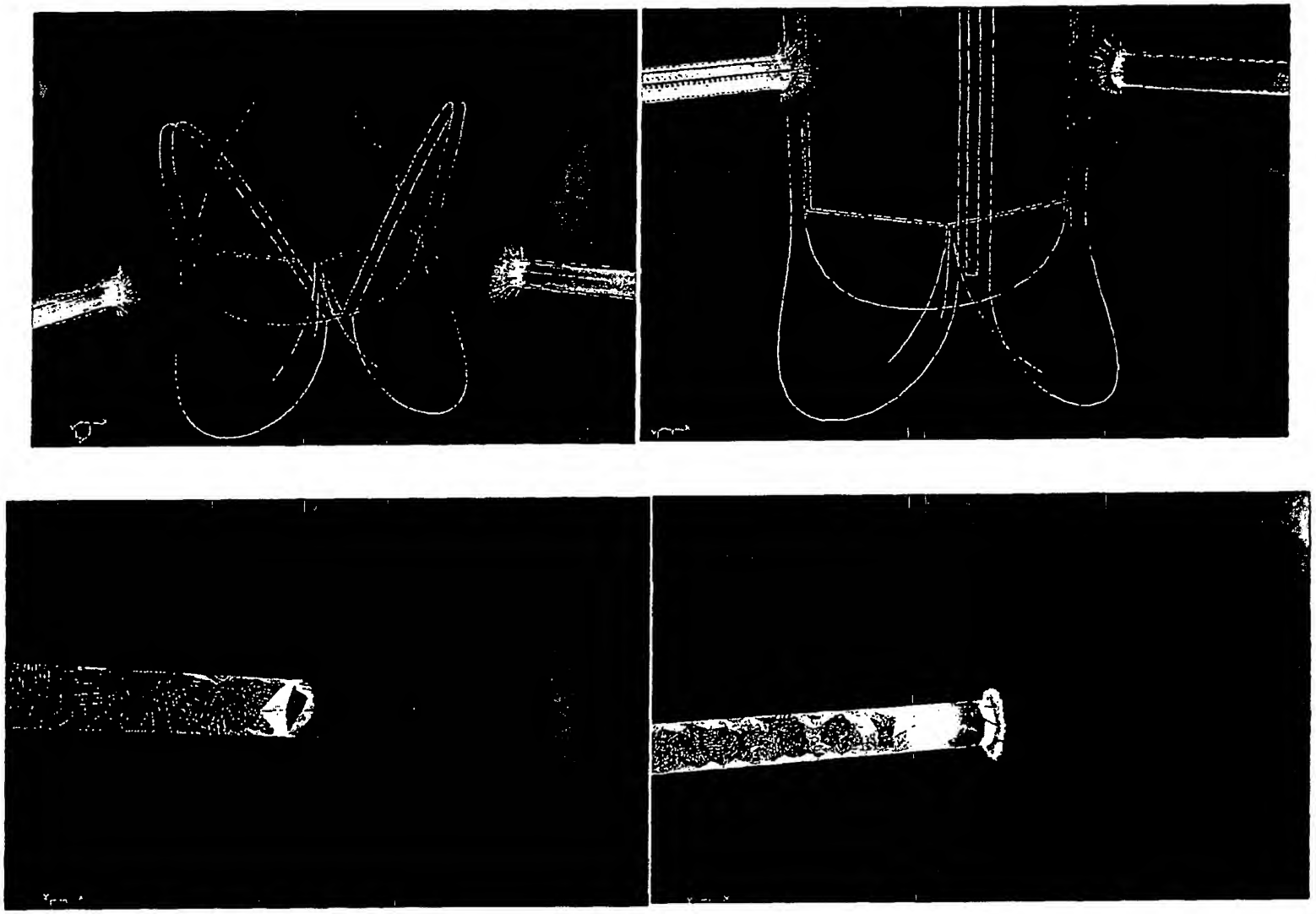

FIG. 3

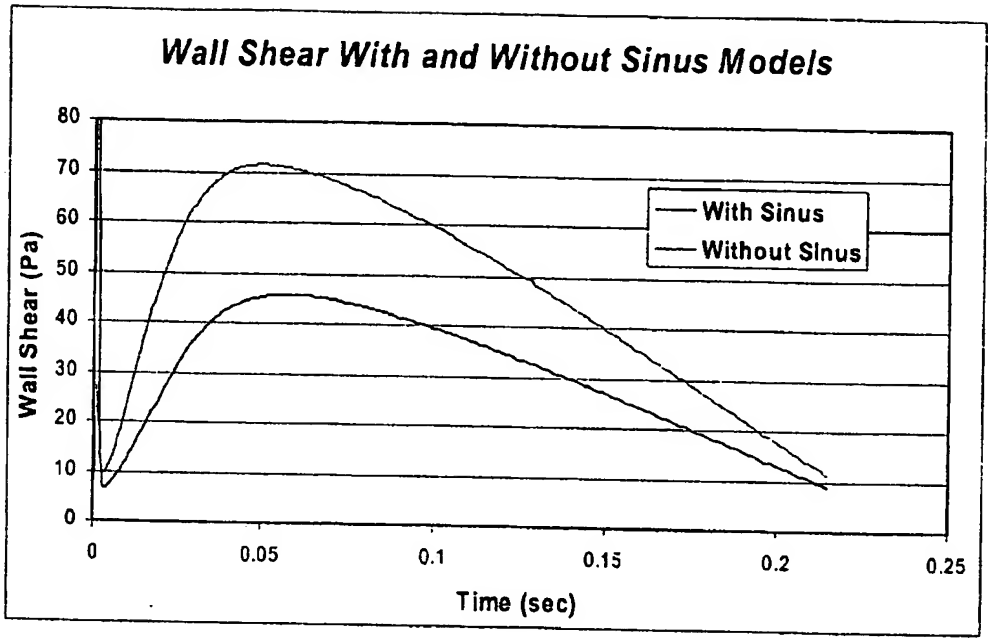
Wall Shear With and Without Sinus Models
Wall Shear (Pa)
80
70
60
50
40
30
20
10
0
0
0.05
0.1
0.15
0.2
0.25
Time (sec)
With Sinus
Without Sinus

FIG. 4

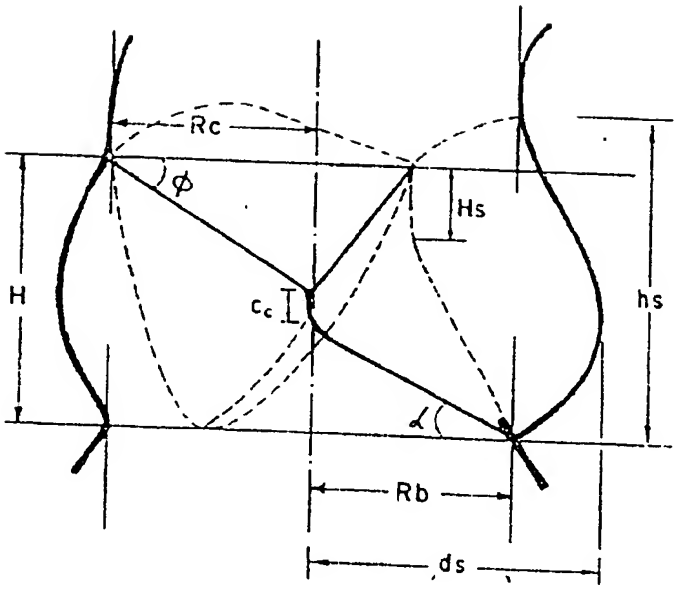

FIG. 5

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